IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA **PUBLIC VERSION**
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	C.A. No. 19-2053-RGA **PUBLIC VERSION**

DEFENDANTS' MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, AND MSN LIFE SCIENCES PRIVATE LIMITED'S BRIEF IN OPPOSITION TO NOVARTIS'S MOTION FOR RULE 62(d) INJUNCTION AND TRO PENDING RESOLUTION OF THIS MOTION

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Novartis's preliminary-injunction motion pending appeal under Fed. R. Civ. P. 62(d) and for a temporary restraining order pending resolution of this motion should be denied since the underlying facts and law set forth in this Court's Trial Opinion holding claims 1-4 of the '659 patent invalid for lack of written description remain undisturbed. Thus, the Court need not second guess itself and thereby deprive the public of a generic sacubitril/valsartan product. Novartis, on the other hand, heavily emphasizes that it will no longer reap monopoly profits on a drug whose patent has been held invalid, which by definition, is *not* irreparable harm. Any harm to Novartis is clearly reparable through an award of damages in the unlikely event that the Federal Circuit later overturns this Court's invalidity finding. Novartis thus fails to demonstrate that it is likely to succeed on appeal or establish any irreparable harm. Moreover, both the balance of hardships and the public interest weigh against entry of any injunction.

The case on appeal—but now before this Court on an injunction motion to block MSN's launch—is one of many in which Novartis has fought to protect its blockbuster Entresto® franchise. Closing in on $4B in sales for 2024, Entresto® has been one of Novartis's single best-selling drugs. Novartis's claims of financial harm in the face of generic competition is unavailing. As explained in the accompanying declarations of DeForrest McDuff, Ph.D. and Bharat Reddy Chintapally, Novartis's purported financial harm is not irreparable and MSN is sufficiently capitalized and financially positioned to compensate Novartis through an appropriate damages award for a launch should it be found liable to Novartis.

At bottom, Novartis's argument is that it stands to lose several billion dollars of revenue. But Courts have emphatically rejected the idea that such monetary damages constitute irreparable harm and can be addressed, if necessary, via monetary relief. MSN respectfully asks the Court to deny Novartis's extraordinary request for relief.

LEGAL STANDARDS

Third Circuit law applies to an injunction pending appeal under Rule 62(d) because an injunction pending appeal is an "issue[] not unique to patent law." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 841 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011); *see also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). The Third Circuit has recognized that the standard for an injunction pending appeal "is essentially the same as that for obtaining a preliminary injunction," which "is an extraordinary remedy never awarded as of right." *Conestoga Wood Specialities Corp. v. Sec'y of U.S. Dep't of Health & Human Servs.*, No. 13-1144, 2013 WL 1277419, at *1 (3d Cir. Feb. 8, 2013); *see also Reilly v. City of Harrisburg*, 858 F.3d 173, 177 (3d Cir. 2017), as amended (June 26, 2017); *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted."). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); Conestoga, 2013 WL 1277419, at *1 (in order to be awarded such extraordinary relief, a party must demonstrate "(1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief."); *see also Reilly*, 858 F.3d at 176 ("[A] movant for preliminary equitable relief must meet the threshold for the first two 'most critical' factors" before the "court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief.")

If Novartis fails to carry its burden on either of the first two elements, no injunction may issue. *See., e.g, Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014). Here, all four elements weigh in favor of denying the injunction.

I. Novartis fails to show that it is likely to succeed on appeal.

The Court held the '659 patent invalid for lack of written description, finding that the inventors of the '659 patent "axiomatically" could not be in possession of a non-covalently bound complex of sacubitril and valsartan that was unknown as of the priority date of the '659 patent. Trial Op. at 44 (D.I. 1099). Though Novartis "respectfully submits that the Federal Circuit is likely to conclude the Court erred in arriving at that conclusion" (Novartis Brief at 4), the Court's factual findings are unlikely to be found to be clearly erroneous on appeal under present written description jurisprudence. Indeed, Novartis's arguments on the merits are the same as those the Court already rejected on the first go-around. In the case of a preliminary injunction, "[if defendant] raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001). Here, the Court not only found that there was a substantial question on the validity of the '659 Patent but actually found the patent invalid under the higher clear and convincing standard. That alone should suffice to defeat this motion. *See Reebok Int'l Ltd. v. J. Baker Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) ("[A] district court may properly deny a motion for preliminary injunction simply based on the movant's failure to establish a reasonable likelihood of success on the merits.").

Claim construction played a critical part in the Court's invalidity decision. Notably, before trial, the parties disputed the construction of the following phrases in the '659 Patent:

> administered in combination / administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms . . . .

At the time, the sole dispute was "whether the phrase should be limited to the active agents valsartan and sacubitril as two separate components, as MSN proposed, or not so limited as Novartis proposed." *See* D.I. 294 at 5. After the claim construction hearing, Judge Stark, who was presiding over the case at the time, ultimately adopted Novartis's construction and construed the phrase to mean:

> wherein said (i) . . . and said (ii) . . . , are administered in combination / administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered *in one unit dose form or in two separate unit dose forms*

Id. (emphasis added).

Judge Stark noted that Novartis's argument relied on the fact that "[n]othing in the specification of the '659 and '331 Patents limits the claims," but he further noted that the specification "discloses combinations of physically separate valsartan and sacubitril and does not disclose the later-invented compound of valsartan and sacubitril (wherein valsartan and sacubitril salts are associated with non-covalent bonds)." *Id.* at 6. Indeed, in adopting this construction, Judge Stark held that the "absence of any indication in the written description that the patentee limited its invention solely to separate compounds means, in context, that a person of ordinary skill in the art would not read the claims as so limited." *Id.*

Moreover, the Court noted that "Novartis admits that its two patents 'do not disclose or suggest' a one-unit-dose-form embodiment. . . . This seems to be an admission by Novartis that, at the very least, there will be a non-frivolous issue of written description and/or lack of enablement as this case proceeds on Novartis' preferred construction." *Id.* at 7. Judge Stark's statement would prove prophetic as this construction later led to the invalidity of the '659 Patent.

In finding the '659 Patent invalid for lack of written description, the Court held that "[t]he touchstone of written description is possession [of the claimed invention] as of the priority date," and that "in 2002, complexes of valsartan and sacubitril, pharmaceutical complexes, and complexes, generally, were unknown to a POSA." Trial Op. at 44 (D.I. 1099). Accordingly, "'the [Novartis] scientists, by definition, could not have possession of, and disclose, the subject matter of [such complexes]' in 2002, and therefore, 'axiomatically, [plaintiff] cannot satisfy the written description requirement for such complexes.'" *Id*.

In reaching this conclusion, the Court noted that Novartis could not avoid invalidity for lack of written description because the specification describes only a physical mixture of valsartan and sacubitril, *not complexes*. *See, e.g.,* '659 Patent at 2:46-49 (discussing that EP Appl. No. 498361 discloses "a combination of certain Ang II antagonists or certain renin inhibitors with certain NEP inhibitors"); 2:50-56 (discussing that EP Appl. No. 726072 discloses "a combination of" an Ang II antagonist and a NEP inhibitor); 3:30-5:45; 5:45-46 ; 6:53-55; 7:33-10:2; and 11:24-31. In fact, as Judge Stark noted during claim construction briefing, Novartis conceded that "[t]he '659 . . . Patent specification discloses combinations of physically separate valsartan and sacubitril and does not disclose the later invented compound of valsartan and sacubitril (wherein valsartan and sacubitril salts are associated with non-covalent bonds)." Claim construction opinion at 10 (D.I. 294) (*citing* '659 Patent, 12:15-17). Based on these facts, the Court held that this limited disclosure fails because "common structural features [must] be described 'with enough precision that a relevant artisan can visualize or recognize the members of the genus.'" *Id*. at 45. And the only combination described in the patent specification is a physical separate mixture of sacubitril and valsartan, *not* a covalently-bonded complex of the two compounds.

Critically, the Court reached this opinion because Novartis successfully argued for the claim construction discussed above that captured both complexes and mixtures. Having done so, both mixtures of sacubitril and valsartan as well as covalently-bonded complexes of sacubitril and valsartan are within the scope of this construction, despite the intrinsic and extrinsic evidence being silent as to the complex. The Court also based its invalidity finding on Novartis's own repeated arguments that a POSA in 2002 did not and could not have known about complexes covered by the claims of the patent. *Id*.

Thus, to overturn this finding on appeal, Novartis has argued that the Court "misinterpreted precedent and overlooked undisputed facts." (Novartis Brief at 4). Not so. As MSN has argued on appeal, the Court properly applied the Federal Circuit's requirement that a written description must lay out common structural features with enough precision for a POSA to recognize the genus. And recent Federal Circuit precedents have repeatedly emphasized this point. *See, e.g., Juno Therapeutics, Inc. v. Kite Pharma, Inc.,* 10 F.4th 1330, 1338 (Fed. Cir. 2021) and *Biogen Int'l GMBH v. Mylan Pharms*., 18 F.4th 1333 (Fed. Cir. 2021). Notably each of those cases found a lack of written description where the specification is either devoid of any disclosures or extremely limited to enable a broad genus.

That mirrors the case here, where claims are directed to a genus of "combinations" of sacubitril and valsartan, and mixtures and complexes of sacubitril and valsartan were a subset of the claimed genus, but the specification is entirely silent on complexes. In fact, as the Court noted, "the '659 Patent specification describes physical mixtures only. The specification did not, and could not, have allowed a POSA to visualize the members of the entire genus sufficient to show possession of complexes, which, to a POSA's knowledge, had not yet been discovered."

Trial Op. at 45. As such, reversal on the merits is unlikely, and Novartis is unlikely to succeed on appeal.

II. An injunction pending appeal of an invalidated patent is rare.

Injunctions pending appeal are rarely granted to a patent owner whose patent is found invalid or not infringed at trial. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762 (JAP), 2009 WL 1968900, at *4 (D.N.J. July 1, 2009) (denying injunction pending appeal in ANDA case after judgment of non-infringement); *Warner Chilcott Co., LLC v. Teva Pharm. USA, Inc.*, No. 1:08-cv-00627-LPS, D.I. 420, 423 (D. Del. June 6, 2014) (denying injunction pending appeal in ANDA case after judgment of invalidity); *Senju Pharm. Co. v. Lupin Ltd.*, No. 11-271-SLR, D.I. 209 (D. Del. Aug. 26, 2013) (denying injunction pending appeal in ANDA case after invalidating patent-in-suit); *cf. Duramed Pharm., Inc. v. Watson Labs., Inc.*, No. 3:08-cv-0116-LRH-RAM, D.I. 295 (D. Nev. June 16, 2011) (denying preliminary injunction where Federal Circuit reversed summary judgment of non-obviousness and remanded to consider secondary considerations). An injunction is not guaranteed or even presumptively available when a patentee *wins*. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006). Having *lost*, Novartis should certainly not be entitled to an injunction.

III. Novartis's alleged harms are not irreparable.

Novartis alleges potential price erosion, loss of market share, loss of profits, loss of research opportunities, and the potential layoffs of salespeople as the purported irreparable harms it will suffer if MSN is permitted to launch its generic product. None of these alleged harms withstands scrutiny. "The mere loss of money is not irreparable harm so long as the litigant can be made whole through money damages." *Akal Sec., Inc. v. U.S.*, 87 Fed. Cl. 311, 319 (2009). These measures of damages, dealing with the sales of a product in a mature and well-defined market, even if suffered, are routinely identified and calculated by economic experts in these

types of cases. *See* McDuff Decl. ¶¶ 10-17; *see also Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009) (affirming finding of no irreparable harm despite the patentee's allegations of price erosion, loss of market share, loss of profits, loss of research opportunities, and possible layoffs). As Dr. McDuff explains, some degree of uncertainty and resulting estimation is inherent in almost every damages analysis, but that does not make the underlying harm irreparable. McDuff Decl. ¶ 13. Indeed, Courts have repeatedly found that a generic launch would not cause irreparable harm because any such alleged harm are quantifiable. *See Sebela Int'l Ltd. v. Actavis Labs. FL, Inc.*, No. 17-4789, 2017 WL 4782807, at *7 (D.N.J. Oct. 20, 2017) ("Both loss of market share and price erosion are economic harms and are compensable by money damages even in the context of generic competition in the pharmaceutical industry.") (alteration omitted) (internal citations omitted). In short, courts have found that "damages from loss of formulary positions are reasonably calculable" and that a "loss of tier status will translate into sales losses that should be quantifiable." *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 610 (D.N.J. 2009).

Lost profits (if applicable) are commonly calculated based on the *Panduit* factors, which consider demand for the patented product, availability of non-infringing alternatives, capacity to make lost sales, and the ability to quantify damages. McDuff Decl. ¶ 14 citing *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (Fed. Cir. 1978) and *Rite-Hite Corp. et al. v. Kelly Company, Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). A reasonable royalty (if applicable) is commonly calculated based on the determination of a hypothetical negotiation between licensor and licensee per the *Georgia-Pacific* factors. McDuff Decl. ¶ 14; *see, e.g., AstraZeneca AB et al. v. Apotex Corp.*, F.3d 1324, 1330 (Fed. Cir. 2015). Each of these factors can be determined in ordinary discovery, and these forms of economic damages are frequently evaluated and

quantified by economists in patent infringement matters involving pharmaceuticals and other products. McDuff Decl. ¶ 14. As Dr. McDuff notes, even Novartis's Dr. Vellturo calculates potential harm in the form of lost revenues and profits, supporting the conclusion that any harm in this matter is quantifiable and therefore compensable by remedies at law. *Id.*

Novartis's concerns over potential price erosion—whereby Novartis lowers its price to compete with MSN or other generics—are entirely speculative. As Dr. McDuff notes, Dr. Vellturo acknowledges that "there is considerable variation in observed outcomes in generic entry scenarios." McDuff Decl. ¶ 17 quoting Vellturo Dec. ¶ 50. Branded products often maintain prices or even raise prices when generic competition occurs (due to market segmentation between brand and generic), and so price erosion is not likely to occur unless Novartis chooses the path of price competition. *Id.* Further, prices in a competitive market can adjust to competition, just as they can adjust to a lack of competition should an injunction later be granted. *Id.*

In this case, the purported economic harms Novartis complains about are quantifiable and do not constitute the requisite irreparable harm.

A. Any loss that Novartis may allegedly suffer is easily calculable.

Nor is there any support for Novartis's argument that "[t]he full extent of those losses will be difficult—if not impossible—to calculate. (Novartis Brief at 10 citing Vellturo Decl. ¶¶ 58-62). Even if calculating damages is a complex task, "that alone does not allow a plaintiff to establish irreparable harm." *Chestnut Hill Sound Inc. v. Apple Inc.*, No. 15-261-RGA, 2015 WL 6870037, at *5 (D. Del. Nov. 6, 2015); *Nutrition 21 v. United States*, 930 F. 2d 867, 871 (Fed. Cir. 1991) ("neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction . . .."). These purported harms are present in almost every patent case, yet

injunctions are not automatically granted. *See eBay, 547 U.S. at 391-92*. As Dr. McDuff points out, Novartis's claims regarding "difficulty in forecasting 'but-for' revenues" (Vellturo Decl. ¶¶ 58-62) are overstated and contrary to the underlying data. McDuff Decl. ¶ 18. While there may always be some degree of uncertainty associated with calculating economic damages, there do not appear to be any factors that make the calculation particularly difficult in this case. *Id.*

In fact, the pharmaceutical market has been analyzed numerous times using and creating financial models to calculate and predict potential damages. And when quantifying damages, financial and economic experts routinely address the purported challenges associated with additional market entrants, price erosion, and promotional activity. *See Sebela,* 2017 WL 4782807, at *7 (finding calculable damages even though the "damages might be significant," and the pharmaceutical industry is complex). As Dr. McDuff notes, "there are no factors here that make a damages determination particularly unusual or difficult." McDuff Decl. ¶ 19. This is particularly the case where any potential damages are known and limited. Additionally, if it prevails at trial, Novartis "will be able to recover damages . . . for past patent infringement," and thus has not "shown a likelihood of irreparable harm." *Teva*, 572 U.S. at 1301 (refusing to block at-risk generic launch pending review of patent invalidity finding).

B. MSN has the financial wherewithal to compensate Novartis for any losses it may suffer.

Although Novartis speculates that "MSN is unlikely to be able to pay Novartis for [its] loses" (Novartis Brief at 11), there is no truth to that. As explained in the Chintapally declaration, MSN is itself a billion-dollar company. Chintapally Decl. ¶ 3; McDuff Decl. ¶ 22. And MSN is one of the fastest growing generic pharmaceutical companies, with considerable experience in at-risk launches and the planning and strategies behind them. Chintapally Decl. ¶¶ 4-5; McDuff Decl. ¶ 23. Based on Novartis's publicly reported guidance and MSN's own calculations for the

period between [redacted] (the same period Novartis and Dr. Vellturo use), [redacted] Chintapally Decl. ¶¶ 6-9; *see also* McDuff Decl. ¶ 21. That figure alone, escrowed by MSN, would be sufficient to cover any lost profits to Novartis's due to MSN's launch during the period. Chintapally Decl. ¶ 8-10; McDuff Decl. ¶ 22. Moreover, MSN's current financial condition based on available cash, reserves, anticipated profits, receivables and inventory would allow it to cover any shortfall. Chintapally Decl. ¶ 11; McDuff Decl. ¶ 22-23. Finally, MSN has both access to insurance to cover any judgment awarded to Novartis, as well as the ability to control and limit its launch to mitigate its exposure. Chintapally Decl. ¶ 12-13; McDuff Decl. ¶ 27. Thus, contrary to Novartis's belief, MSN is well positioned financially to satisfy any judgment that may later be awarded against it should the Court's invalidity finding be overturned on appeal. McDuff Decl. ¶ 29.

IV. The balance of equities and public interest weigh against an injunction.

Assessing the balance of hardships and determining whether an injunction would disserve the public interest are "highly factual inquiries." *Apple*, 678 F.3d at 1332. An injunction would deny MSN the ability to launch its product and deprive it of significant revenue; a product that took MSN years to develop, as well as years to litigate to a successful conclusion. [redacted] and in demonstrating that Novartis's '659 Patent is invalid. Chintapally Decl. ¶ 15; McDuff Decl. ¶ 34. Moreover, MSN has incurred significant costs in the steps taken to prepare for a commercial launch of the product. *Id.* It has several months' worth of finished product ready to launch and several months' worth more in the pipeline. *Id.* MSN would suffer considerable harm if it were enjoined from selling its product. *Id.* That harm would have further

ripple effects as to MSN's future business plans and other products in its portfolio. *Id.* MSN recently received final approval from the FDA, and if it is blocked from launching it may not be able to recoup these investments.

Generic entrants frequently compete for position based on time to market, and MSN may lose a significant first-mover advantage if it is not allowed on the market when it is ready to launch. McDuff Decl. ¶ 34. A preliminary injunction will allow other generic competitors to better prepare to compete with MSN and may erode MSN's market opportunity almost entirely. *Id.* Accordingly, on a percentage basis of its overall sales, MSN has more to lose from *not* being able to come to market than Novartis has to gain by keeping MSN off the market. *Id.* Then, after accounting for any compensation Novartis may seek, the primary loss associated with an injunction would be to MSN. *Id.* Thus, if anything, the balance of hardships weights against entry of an injunction.

The public interest is a weighing of factors: protecting innovators, on the one hand, and allowing competition, on the other hand, among other things. Novartis does not seriously contend with this balancing. Here, an injunction would significantly harm not just MSN, but patients and payors too. Given Entresto's nine years of exclusivity on the market and more than $12 billion earned in the U.S. since launch in 2015 (*see* McDuff Decl. ¶ 38 citing Exhibit B-1), a reasonable case can be made that Novartis has already been fairly compensated for its investment in bringing a new product to market. *Id.* Any additional compensation that Novartis should have further earned due to patent exclusivity can be sorted out after an injunction, if needed. *Id.* If Novartis is as concerned about making sacubitril/valsartan available to those in need as it claims, the availability of a generic alternative on the market will do just that. McDuff Decl. ¶ 40 ("any decrease in future awareness, even if it exists, is likely to be far less than the public benefit of

lower prices for patients and resulting increased demand that can result from generic competition."). Nor is Novartis being *forced* to reduce its detailing and patient education efforts; it may only choose to do so because its revenue from Entresto® would be reduced. (Novartis Brief at 11-12); McDuff Decl. ¶¶ 28-29. This claimed effect is dubious as an economic matter; neither Novartis's ability nor incentive to continue these investments would change materially with MSN's entry. McDuff Decl. ¶ 40. Moreover, Third-party payors, Medicare, and Medicaid represent most annual payments for prescription drugs. Timely marketing of generic competition will contribute to increasing drug access to the public. An injunction would thus reward Novartis by artificially extending its ability to charge monopoly prices, at the expense of the public. On balance, the public interest does not favor an injunction.

CONCLUSION

For the foregoing reasons, the Court should deny Novartis's request for an injunction pending appeal, as well as for a temporary injunction pending resolution of this motion.

Dated: August 6, 2024

Respectfully submitted,

STAMOULIS & WEINBLATT LLC

/s/ Richard C. Weinblatt
Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
800 N. West Street, Third Floor
Wilmington, DE 19801
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

Of counsel:
Ronald M. Daignault*
Richard Juang*
DAIGNAULT IYER LLP
8229 Boone Blvd., Suite 450
Vienna, VA 22182

rdaignault@daignaultiyer.com
rjuang@daignaultiyer.com
**Not admitted in Virginia*

Attorneys for Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2024, I caused a copy of the foregoing document to be served by e-mail to the following counsel listed below.

Daniel M. Silver
Alexandra M. Joyce
MCCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
dsilver@mccarter.com
ajoyce@mccarter.com

Nicholas N. Kallas
Christina Schwarz
Christopher E. Loh
Susanne L. Flanders
Jared L. Stringham
Shannon K. Clark
Laura K. Fishwick
Gregory J. Manas
VENABLE LLP
1290 Avenue of the Americas
New York, New York 10104
nkallas@venable.com
cschwarz@venable.com
cloh@venable.com
slflanders@venable.com
jlstringham@venable.com
skclark@venable.com
lfishwick@venable.com
gjmanas@venable.com

/s/ Richard C. Weinblatt
Richard C. Weinblatt (#5080)